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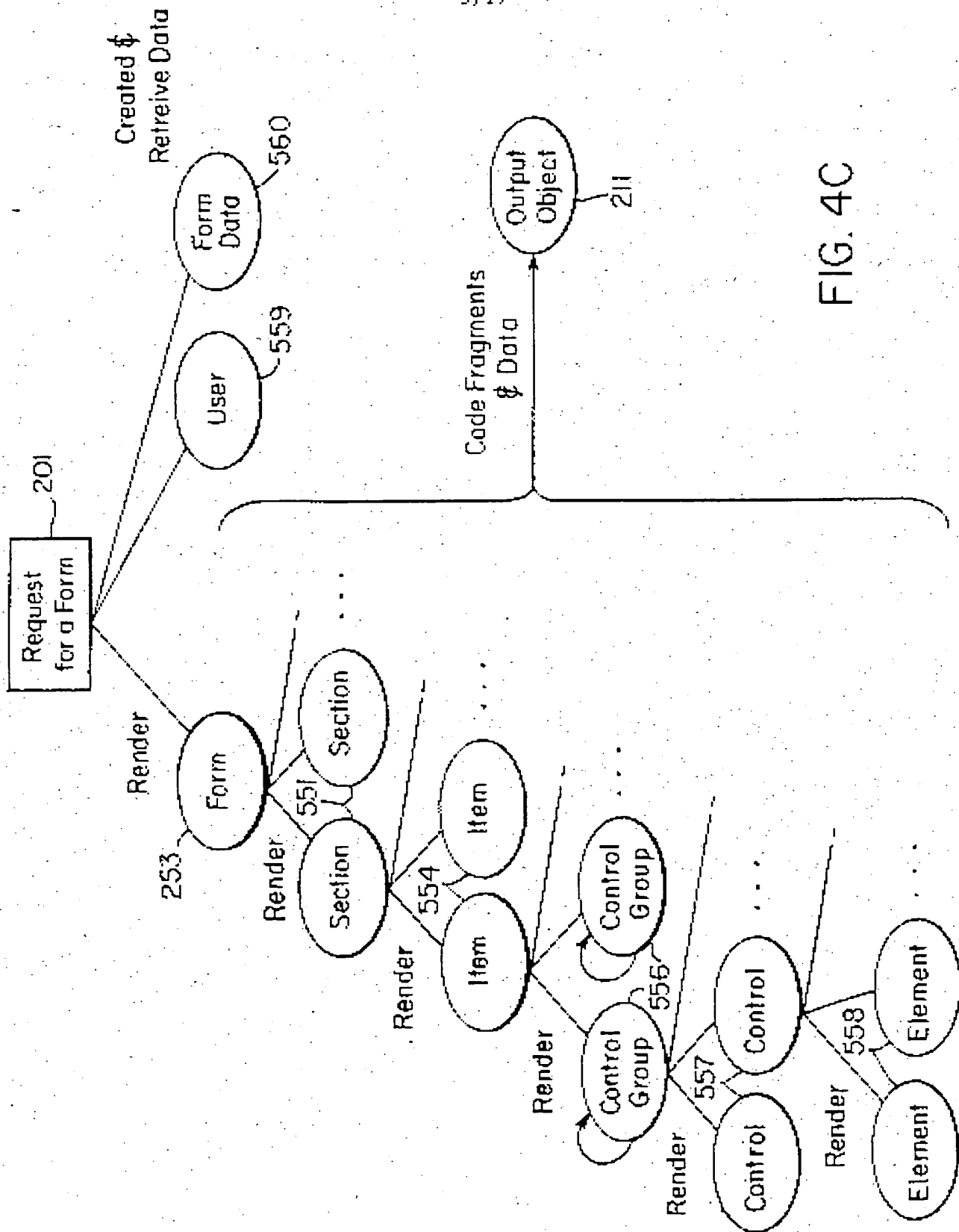


FIG. 4C

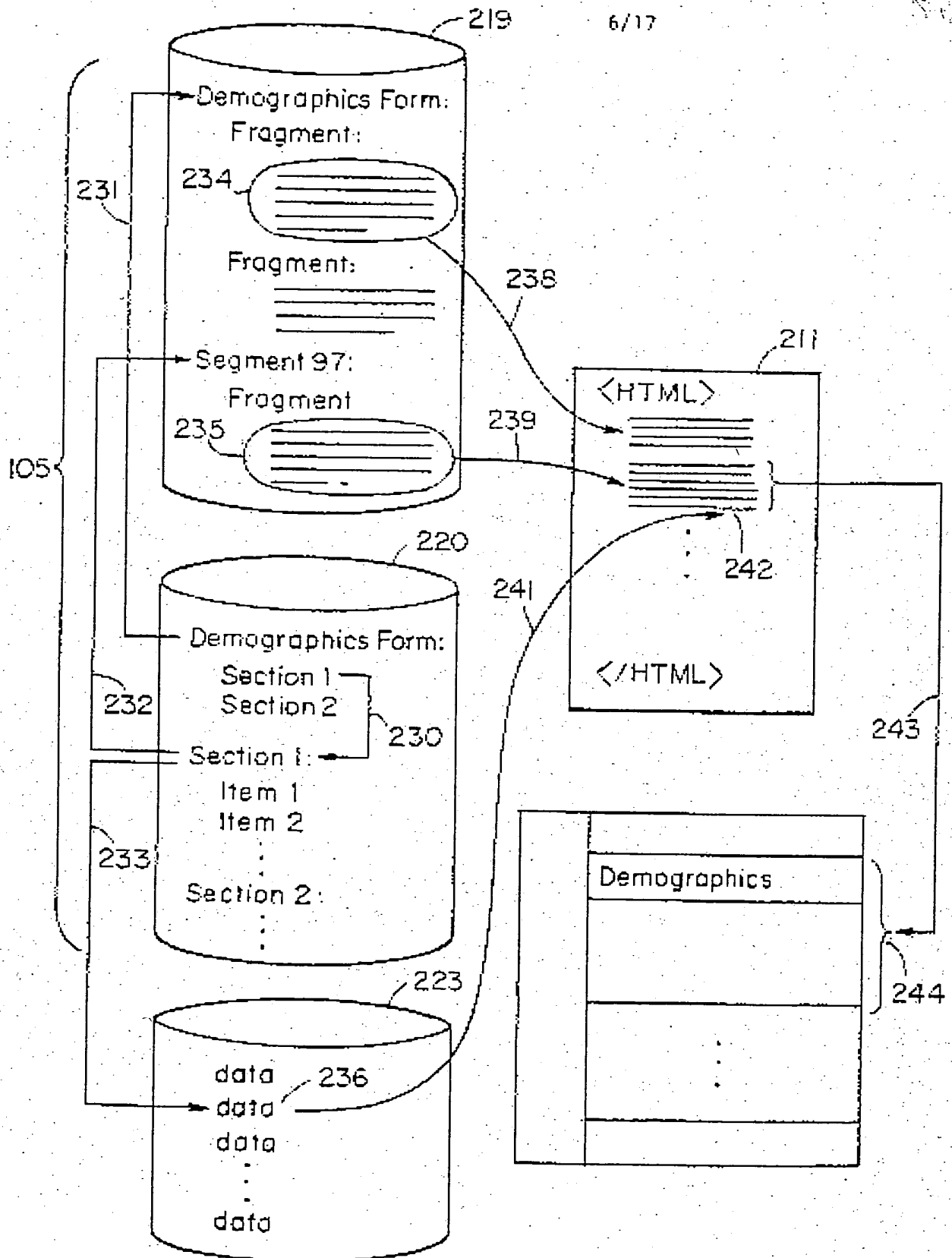


FIG. 4D

275      7/17      251B

John E. Raymond  
Laboratory Assistant

Home | Help | Logout  
Enrollment  
Visits  
Queries  
Status  
Documents  
Signatures  
Monitor

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251A

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8  
IF DEM HH ES PE VS/EP ECG/CXR LAB CM

Demographics      ■ Ready for SDV      Patient: JPK      Patient No: CI-DOJ

Demographics

1. Gender: Female

2. Date of Birth: Feb 19, 1954

3. Race/Ethnic Origin: Black

4. Height: 66 in

5. Weight: 145 lb

6. Frame: Medium

Calculated weight/ variance from avg.      — % Above/Below

Smoking History

7. Has patient ever smoked? No  
*You indicated that the patient smokes cigarettes in item 9. Please check that as it is the correct answer to "Has the patient ever smoked?"*

8. If the patient has ever smoked, has the patient quit smoking? No

9. If the patient currently smokes, the patient smokes: Cigarettes

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1

Next Reverse Exit

251C

FIG. 5

291

# PHASE FORWARD

## InForm™

Please enter your name and password

Account name: jsmith

Password: \_\_\_\_\_

Log in

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FIG. 6

8/17

Jennifer Smith, RN  
Clinical Research  
Coordinator

Home Help Logout

Enrollment

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Documents

JPH/OIWk-4 Dem  
JPH/QI-Wk-4 ECG  
JPH/QI-T&E Sched  
Site OI GRBs

## PHASE 3

### PF-105 Clinical Drug Trial

#### Study News

Where Should We Focus Our Efforts? A New Study  
Indicates that the use of **Stavol, P.A. Harner, Mechanisms**  
of Antihypertensives involves an **Anti-Adrenergic**

#### Alerts

Indicates that the use of **Stavol, P.A. Harner, Mechanisms**  
of Antihypertensives involves an **Anti-Adrenergic**

#### Enrollment

Indicates that the use of **Stavol, P.A. Harner, Mechanisms**  
of Antihypertensives involves an **Anti-Adrenergic**

#### January's Top Enrolling Sites

Indicates that the use of **Stavol, P.A. Harner, Mechanisms**  
of Antihypertensives involves an **Anti-Adrenergic**

#### Study Data Process

CRBs to Complete

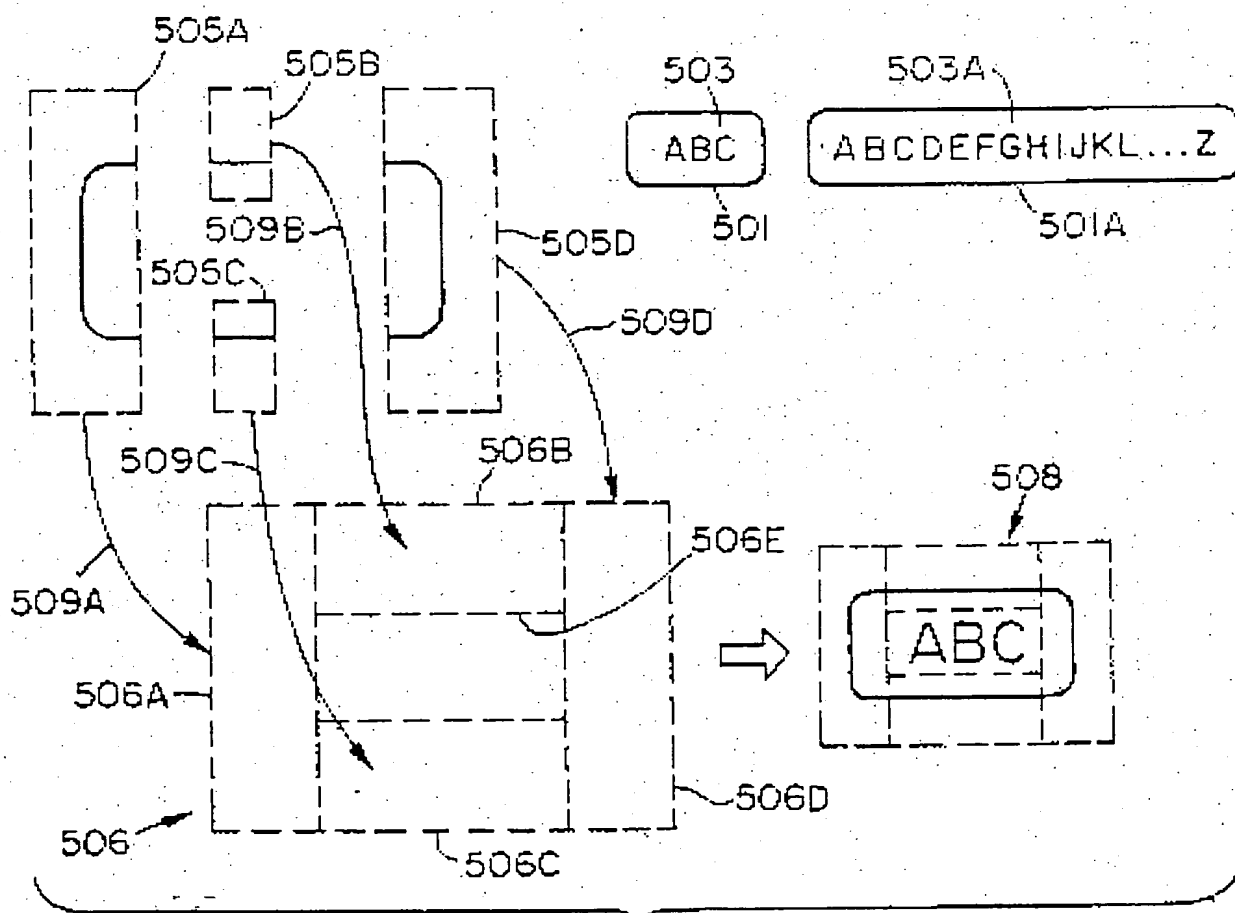
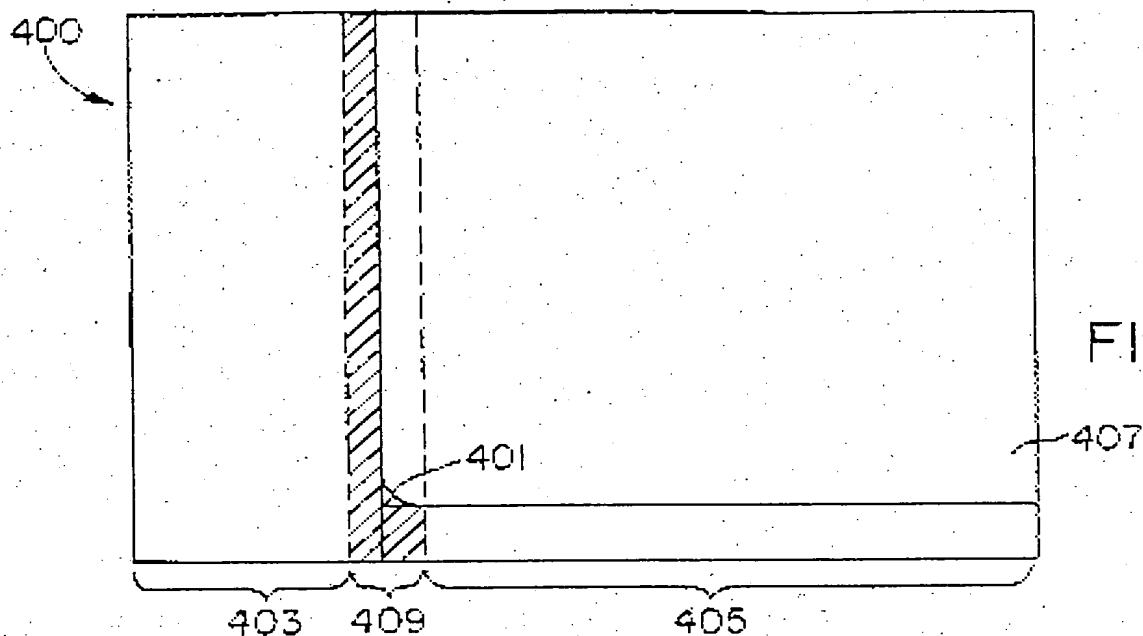
Patients		
Where Should We Focus Our Efforts?	Indicates that the use of Stavol, P.A. Harner, Mechanisms of Antihypertensives involves an Anti-Adrenergic	Indicates that the use of Stavol, P.A. Harner, Mechanisms of Antihypertensives involves an Anti-Adrenergic

Patient No.

Visit

FIG. 7

301



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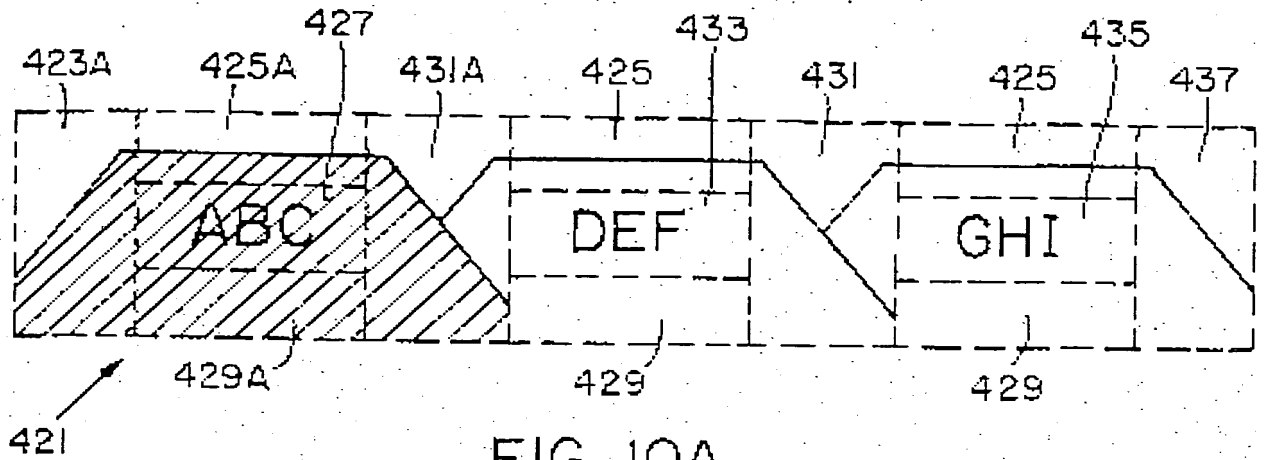


FIG. 10A

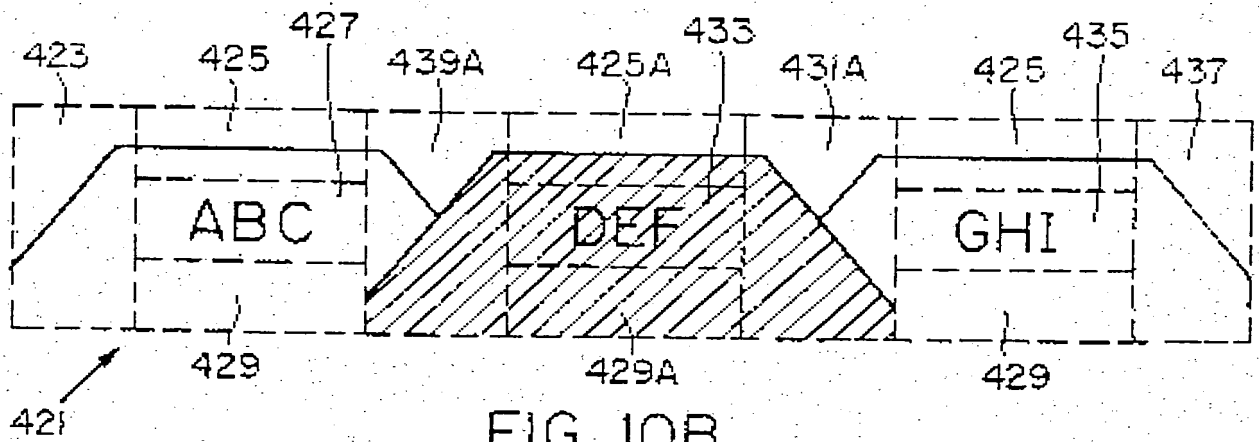


FIG. 10B

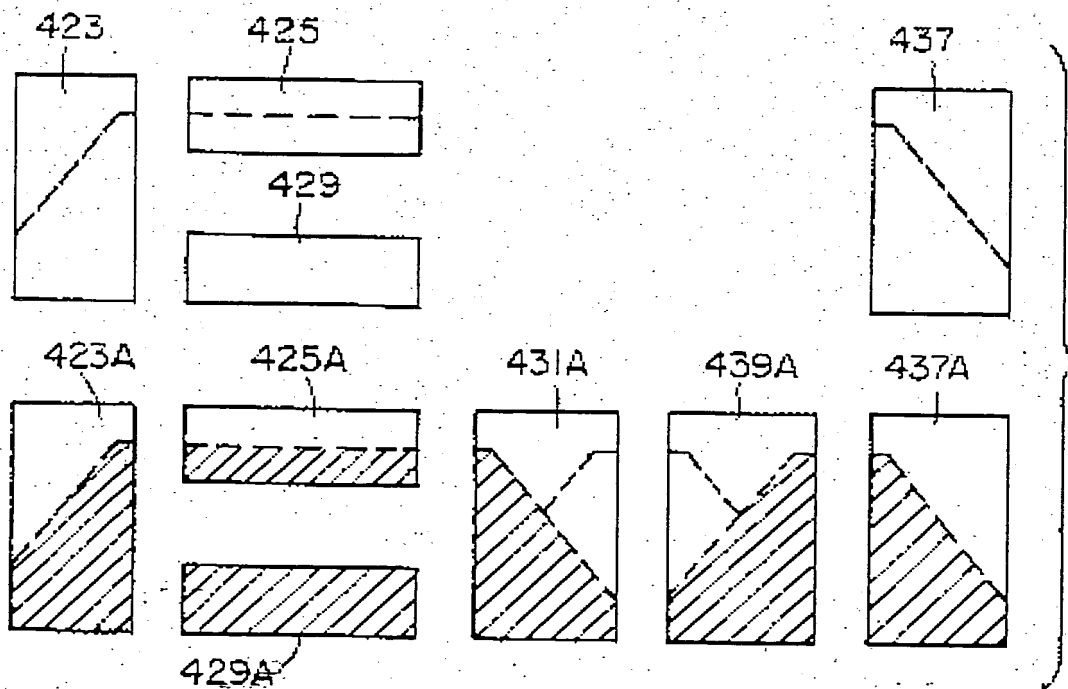
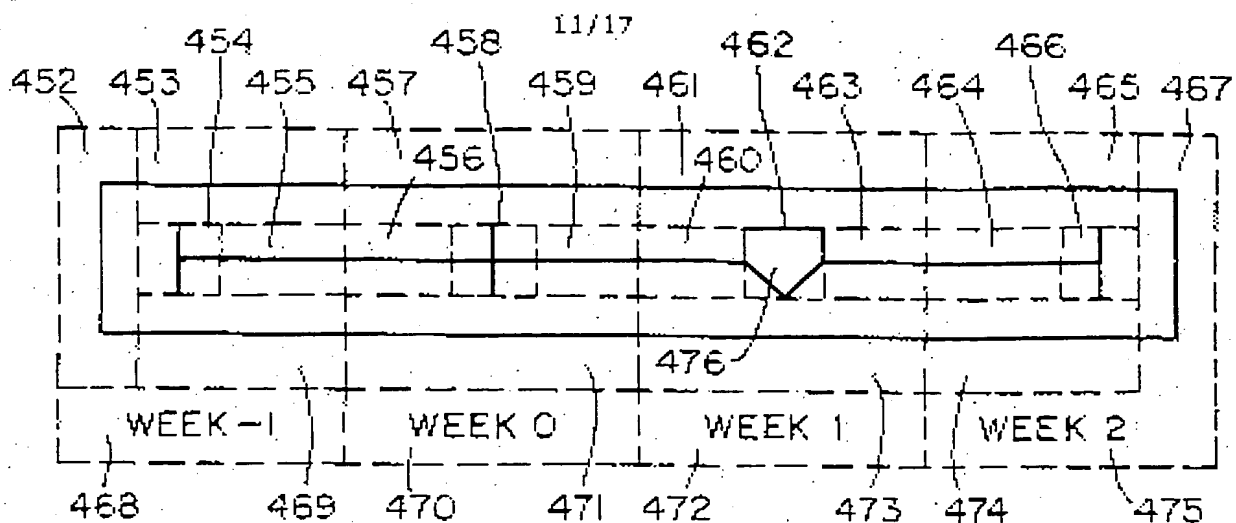


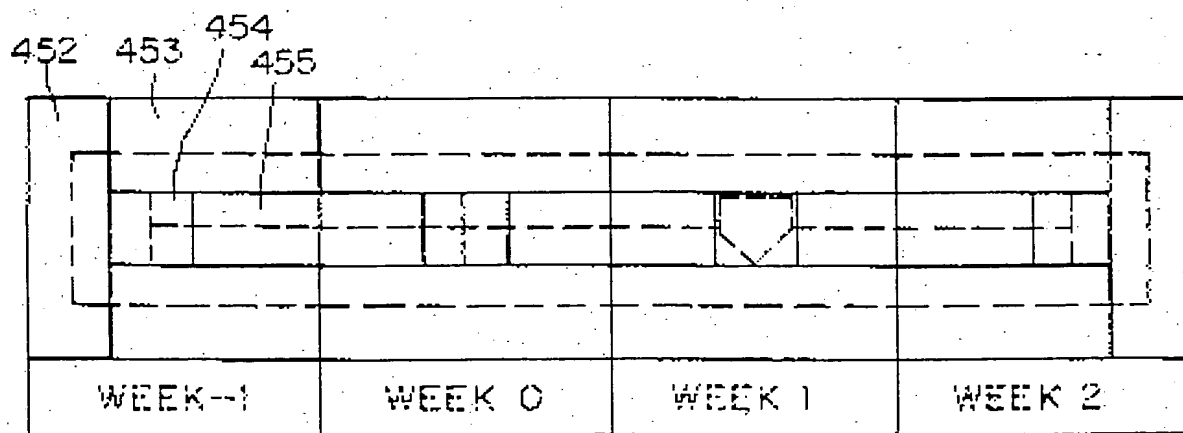
FIG. 10C





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FIG. 11A



451

FIG. 11B

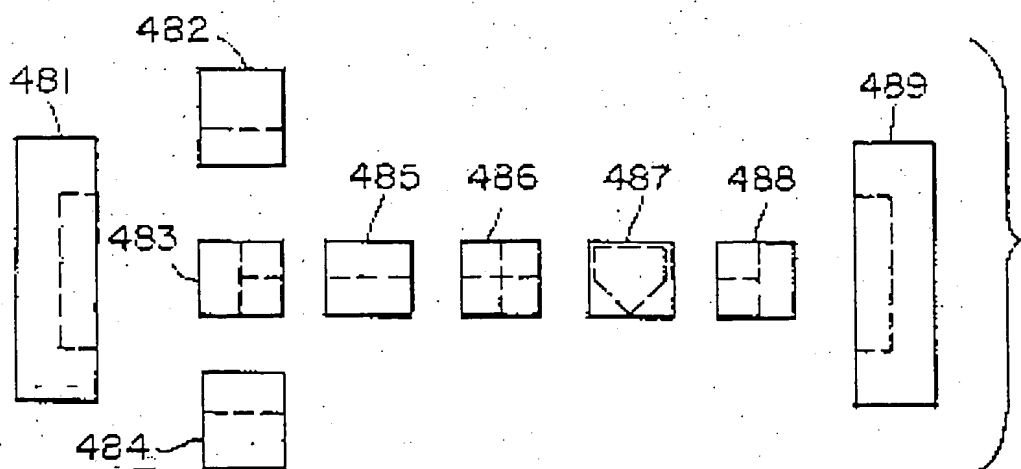


FIG. 11C

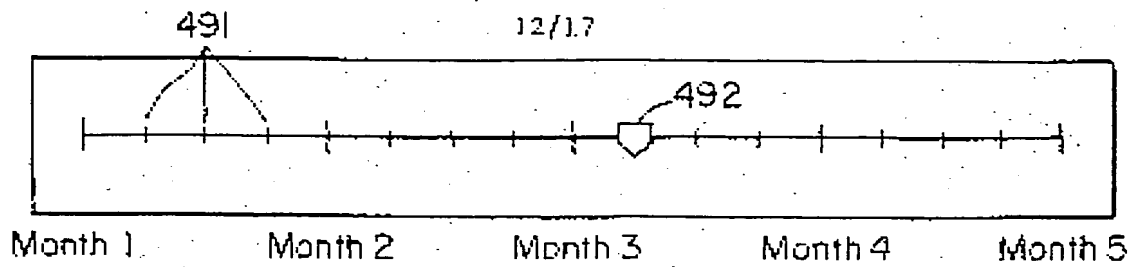


FIG. 11D

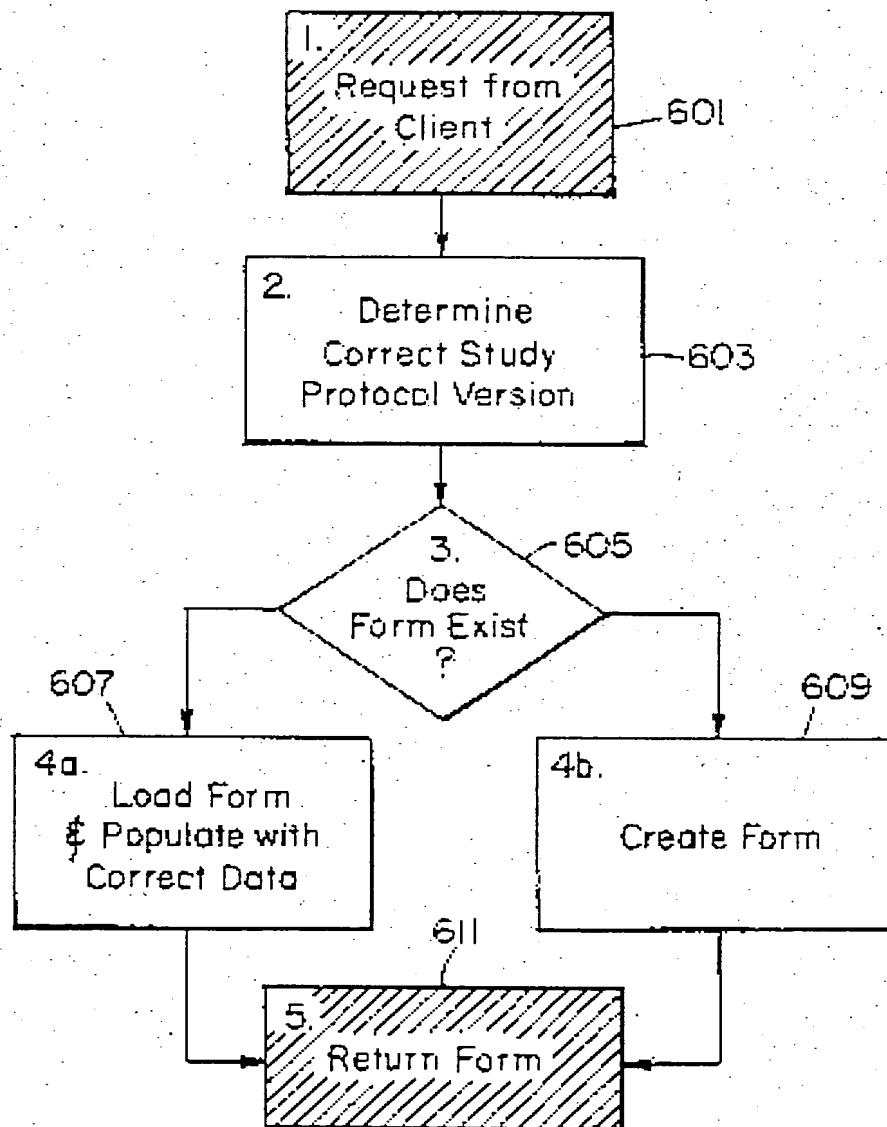


FIG. 12A

PROTOCOL VERSION 1

620

621

623

625

1	Date of Assessment:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2	Blood Pressure Reading 1:	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> Mm Hg	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> Mm Hg
3	Blood Pressure Reading 2:	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> Mm Hg	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> Mm Hg

FIG. 12B

PROTOCOL VERSION 2

1

Date of Assessment:

2

Blood Pressure Reading 1:

3

Blood Pressure Reading 2:

4

Blood Pressure Reading 3:

FIG. 12C

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Help Link  
BO1

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

Demographics

1 Gender ☐ Male ☒ Female

2 Date of Birth Feb 19 1984

3 Race/Ethnic Origin ☒ Black ☐ Other (specify)

4 Height: 66 ☒ in ☐ cm

5 Weight: 145 ☒ lb ☐ kg

6 Frame: Medium

Calculated weight variance from avg. % Above/Below

Smoking History

7 Has patient ever smoked? ☒ Yes ☐ No ☐ Not Done

8 If the patient has ever smoked, has the patient quit smoking? ☒ Yes ☐ No ☐ Not Done

9 If the patient currently smokes, the patient smokes: ☒ Cigarettes ☐ Pipes ☐ Cigars ☐ Not Done

10 If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1  ☐ Unknown ☐ Not Done

Submit Cancel

Home Help Logout

Enrollment

Visits

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Status

Documents

JPK/01/Wk-4 Dem

JPK/01/Wk-4 ECG

JPK/01/T&E Sched

Site DI GRBs

FIG. 13A

Context Sensitive  
Help BO4

Help Window  
BO3

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

Demographics

Item 4 Height

- Height must be measured
- Measure height with shoes off
- Report height in either inches or centimeters. (The entry will be converted to the desired units for report purposes.)

Item 5 Weight

- How should weight be measured?
- Enter the height in the correct unit (inches or centimeters)

Item 6 Frame

- How should frame be measured?
- Enter the frame in the correct unit (inches or centimeters)

Smoking History

9 If the patient currently smokes, the patient smokes: ☒ Cigarettes ☐ Pipes ☐ Cigars ☐ Not Done

10 If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1  ☐ Unknown ☐ Not Done

Submit Cancel

Home Help Logout

Enrollment

Visits

Queries

Status

Documents

JPK/01/Wk-4 Dem

JPK/01/Wk-4 ECG

JPK/01/T&E Sched

Site DI GRBs

Context Sensitive Help BO4

Help Window BO3

FIG. 13B

Help Button  
807

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 Jemifer Smith, MD Clinical Research Coordinator	NAME: <u>THOMAS, WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u> <u>WALTER</u>									
	IT <u>DEM</u> <u>HH</u> <u>SS</u> <u>PE</u> <u>VE/VP</u> <u>ECG/CAR</u> <u>LDR</u> <u>GIA</u> ■ Ready for EDV ■ Patient: <u>MR</u> Patient No: <u>01001</u>									
Demographics										
1. Gender	<input checked="" type="radio"/> Male <input type="radio"/> Female									
2. Date of Birth	FEB <input type="text"/> 19 <input type="text"/> 1954 <input type="text"/>									
3. Race/Ethnic Origin	<input checked="" type="radio"/> Black <input type="radio"/> Other (specify) _____									
4. Height	6' 4" 6' 6" 6' 8"									
5. Weight	145 150 155 160									
6. Height	Medium <input type="text"/>									
Calculated weight percentage from avg. _____ % Above/Below										
Smoking History										
1. Has patient ever smoked?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Other <input type="radio"/> Other Cigar No cigarettes, but has smoked cigars occasionally, please advise exact number of the cigars smoked to determine patient's exposure									
2. If the patient has ever smoked, has the patient quit smoking?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Other Date _____									
3. If the patient currently smokes, the patient smokes:	<input checked="" type="checkbox"/> Cigarettes <input type="checkbox"/> Pipes <input type="checkbox"/> No <input type="checkbox"/> Other <input type="checkbox"/> Other Date _____									
4. If the patient has ever smoked cigarettes, enter the average number of cigarettes smoked per day:	<input checked="" type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 <input type="text"/> 6 <input type="text"/> 7 <input type="text"/> 8 <input type="text"/> 9 <input type="text"/> 10 <input type="text"/> 11 <input type="text"/> 12 <input type="text"/> 13 <input type="text"/> 14 <input type="text"/> 15 <input type="text"/> 16 <input type="text"/> 17 <input type="text"/> 18 <input type="text"/> 19 <input type="text"/> 20 <input type="text"/> 21 <input type="text"/> 22 <input type="text"/> 23 <input type="text"/> 24 <input type="text"/> 25 <input type="text"/> 26 <input type="text"/> 27 <input type="text"/> 28 <input type="text"/> 29 <input type="text"/> 30 <input type="text"/> 31 <input type="text"/> 32 <input type="text"/> 33 <input type="text"/> 34 <input type="text"/> 35 <input type="text"/> 36 <input type="text"/> 37 <input 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280 <input type="text"/> 281 <input type="text"/> 282 <input type="text"/> 283 <input type="text"/> 284 <input type="text"/> 285 <input type="text"/> 286 <input type="text"/> 287 <input type="text"/> 288 <input type="text"/> 289 <input type="text"/> 290 <input type="text"/> 291 <input type="text"/> 292 <input type="text"/> 293 <input type="text"/> 294 <input type="text"/> 295 <input type="text"/> 296 <input type="text"/> 297 <input type="text"/> 298 <input type="text"/> 299 <input type="text"/> 300 <input type="text"/> 301 <input type="text"/> 302 <input type="text"/> 303 <input type="text"/> 304 <input type="text"/> 305 <input type="text"/> 306 <input type="text"/> 307 <input type="text"/> 308 <input type="text"/> 309 <input type="text"/> 310 <input type="text"/> 311 <input type="text"/> 312 <input type="text"/> 313 <input type="text"/> 314 <input type="text"/> 315 <input type="text"/> 316 <input type="text"/> 317 <input type="text"/> 318 <input type="text"/> 319 <input type="text"/> 320 <input type="text"/> 321 <input type="text"/> 322 <input type="text"/> 323 <input type="text"/> 324 <input type="text"/> 3									

FIG. 13C

2514.

Help Window  
809

810
811
809



**Jennifer Smith, RN**  
Clinical Research  
Coordinator

Home

Enrollment

Visits

Queries

Status

Documents

JPH/CH/Week-4 Dem

JPH/OE/Week-4 EC3

JPH/DT/E Sched

Site: C1 GRB5

	Week-4	Week-2	Week-1	Week-2	Week-3	Week-4	Week-5	Week-6	Week-7	Week-8
IF	DEM	HH	SS	PE	VS/BP	ECG/CXR	LAB	CM		

**Demographics** Ready for SDV Patient: JPK Patient No: O-001

**Demographics**

Phase Forward Help-Microsoft Internet Explorer

**Contents** **Index**

**Basics**  
This document is the  
baseline for the  
trial as per the  
protocol and  
introducing CTE

**Introducing CTE**  
This is the first  
step in the trial

**Navigating**  
Overview, but not  
Managing patient  
data

**Monitoring**  
Overview, but not  
Monitoring

Welcome to Clinical Trial Information Environment

The system is a web-based information system that provides the patient with the trial information and the trial status.

- The system is a web-based information system that provides the patient with the trial information and the trial status.
- The system is a web-based information system that provides the patient with the trial information and the trial status.
- The system is a web-based information system that provides the patient with the trial information and the trial status.
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- The system is a web-based information system that provides the patient with the trial information and the trial status.
- The system is a web-based information system that provides the patient with the trial information and the trial status.

**Protocols** **Study Guide** **Help** **Investigator Brochure** **Close**

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:  ☐ Unknown ☐ Not Done

Submit
Cancel

805

FIG. 13D

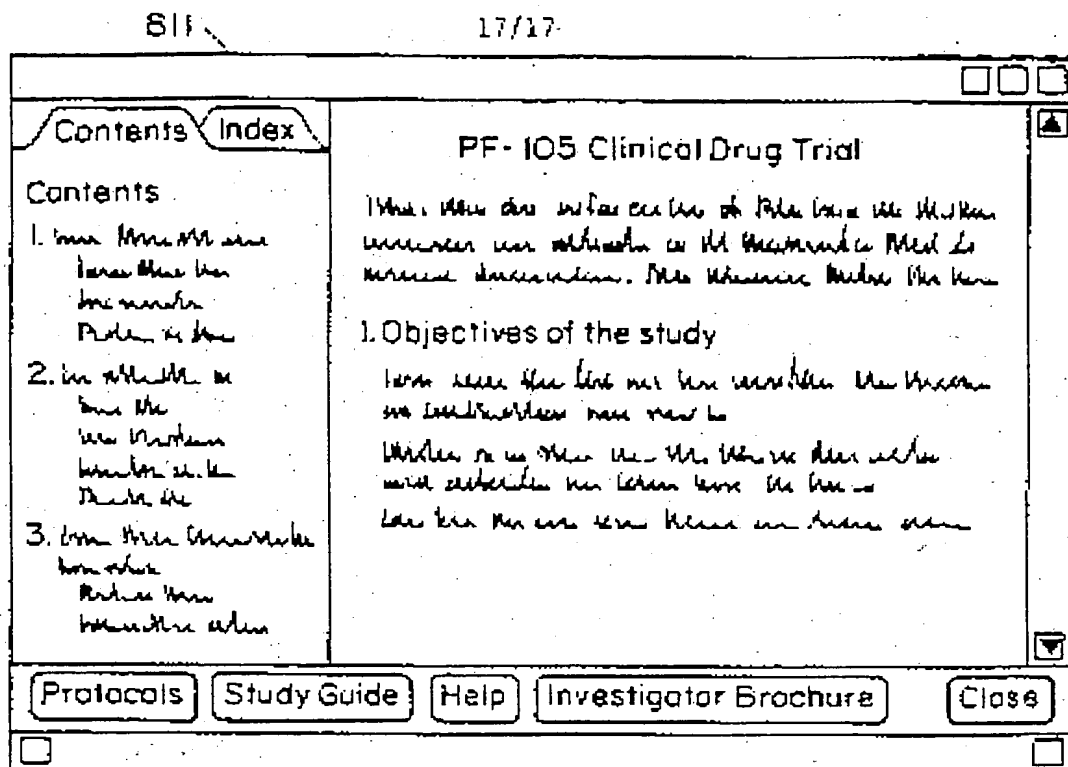


FIG. 13E

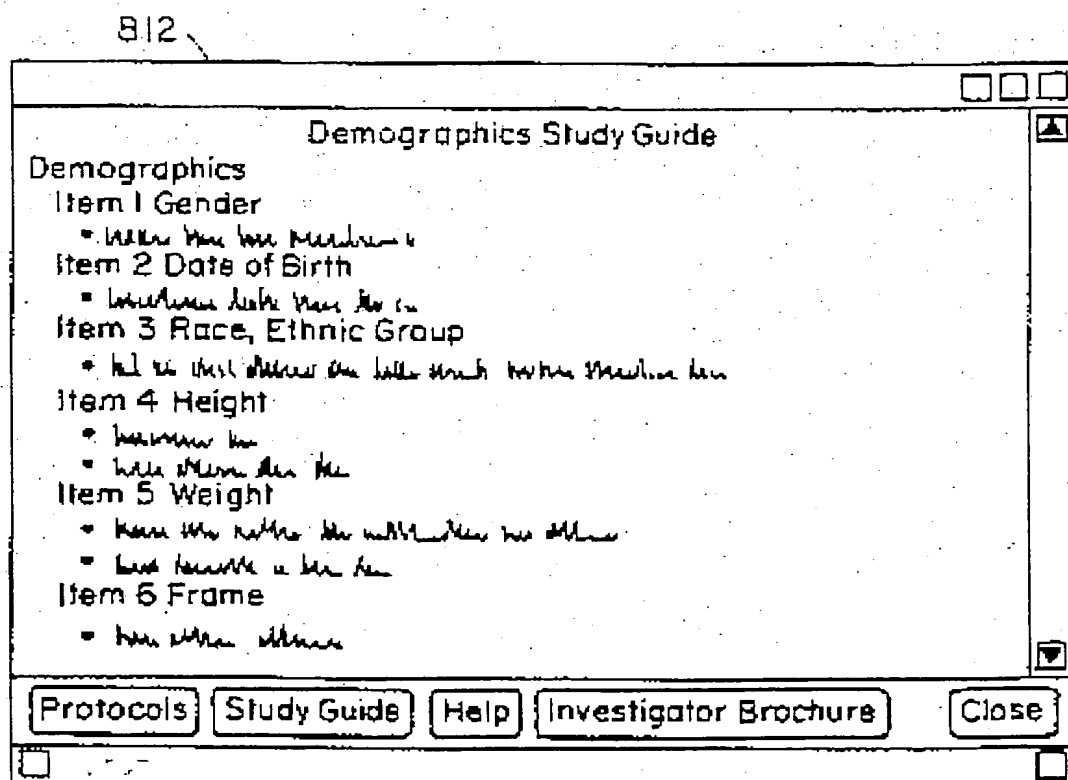


FIG. 13F

3  
C

10





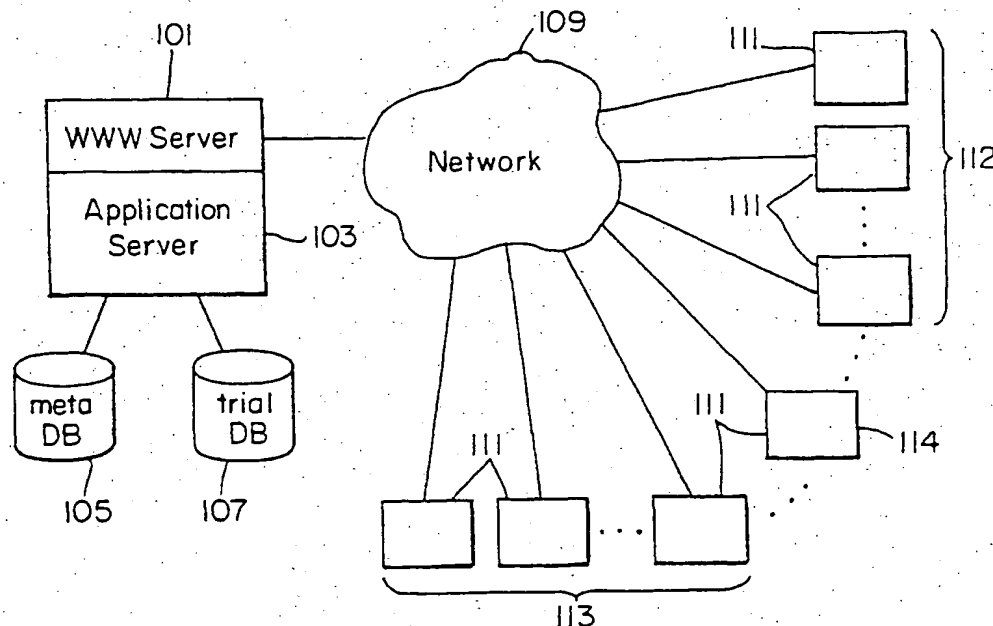
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>G06F 19/00, 9/44</b>		A3	(11) International Publication Number: <b>WO 99/63473</b>
			(43) International Publication Date: 9 December 1999 (09.12.99)
(21) International Application Number: PCT/US99/12406		(81) Designated States: DE, GB, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 3 June 1999 (03.06.99)			
(30) Priority Data: 09/092,441 5 June 1998 (05.06.98) US		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(71) Applicant: PHASE FORWARD INC. [US/US]; 51 Winchester Street, Newton, MA 02461 (US).		(88) Date of publication of the international search report: 27 January 2000 (27.01.00)	
(72) Inventors: BLEICHER, Paul, A.; 174 Mt. Vernon Street, Newton, MA 02165 (US). STAMOS, Nicholas; 22 Jeannette Avenue, Belmont, MA 02478 (US). KLOFFT, Jeffrey, P.; 33 Hamilton Circle, Marlborough, MA 01752 (US). DALE, Richard, M.; 117 Russell Street, Newton, MA 02165 (US).			
(74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, MA 02421 (US).			

(54) Title: CLINICAL TRIAL DATA MANAGEMENT SYSTEM AND METHOD

## (57) Abstract

A system and method for managing clinical trial data includes dynamically generating, at a server, a data entry form to be displayed at a client. The data entry form is generated dynamically in a SGML-derived language. Control elements within the form comprise images which are used to construct the control elements and larger controls. The form is generated from a protocol database and a context received from the client, is populated from the data database, and is published to the client. Templates based on the protocol database comprise several frames including intermediate frames for displaying frame borders which are non-horizontal and non-vertical. If the trial protocol changes during a trial, the generated form is based on the protocol version active at the time data was entered into the form. Inadvertent use of the application is discouraged requiring an authentication procedure and displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each question and information about the question. The source of help may be any or all of a protocol document, an investigative brochure, and a study guide. In addition, a user, upon logging in, is presented with a dashboard screen which provides information or links to information such as trial-related news, alerts, statistical information, progress reports and a list of work to be completed.



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BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

# INTERNATIONAL SEARCH REPORT

Internal Application No.

PCT/US 99/12406

### A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 G06F19/00 G06F9/44

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>KIUCHI T ET AL: "Automated generation of a World Wide Web-based data entry and check program for medical applications" COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE, FEB. 1997, ELSEVIER, NETHERLANDS, vol. 52, no. 2, - February 1997 (1997-02) pages 129-138, XP002123139 ISSN: 0169-2607 the whole document</p> <p style="text-align: center;">— -/-</p>	1-56

☒ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- "Z" document member of the same patent family

Date of the actual completion of the international search

18 November 1999

Date of mailing of the international search report

03/12/1999

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## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/12406

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KELLY M A ET AL: "The Internet and randomised controlled trials" INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS, IR, ELSEVIER SCIENTIFIC PUBLISHERS, SHANNON, vol. 47, no. 1-2, - 1997 page 91-99 XP004107516 ISSN: 1386-5056 the whole document	1-56
A	"MULTI-STATE BUTTON MANIPULATION USING A SINGLE GRAPHIC" IBM TECHNICAL DISCLOSURE BULLETIN, US, IBM CORP. NEW YORK, vol. 38, no. 4, page 585-587 XP000516262 ISSN: 0018-8689 the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	ANONYMOUS: "Efficient 3D Buttons in Dynamic Hyper Text Markup Language Pages" IBM TECHNICAL DISCLOSURE BULLETIN, vol. 41, no. 1, pages 695-698, XP002123140 New York, US the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	GIRGENSOHN A ET AL: "Seamless integration of interactive forms into the Web" COMPUTER NETWORKS AND ISDN SYSTEMS, NL, NORTH HOLLAND PUBLISHING. AMSTERDAM, vol. 29, no. 8-13, page 1531-1542 XP004095347 ISSN: 0169-7552 the whole document	7-17, 42
A	NETSCAPE COMMUNICATIONS CORP.: "NetHelp" NETHELP RELEASE 1.0 SDK DOCUMENTATION, 'Online!' - August 1996 (1996-08) pages 1-14, XP002071214 USA Retrieved from the Internet: <URL: http://home.netscape.com/eng/help/sdk1/sdksite.htm> 'retrieved on 1998-07-10! the whole document	7-17, 42